UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

DEBRA SIMS	§	
	§	
Plaintiff,	§	
	§	
v.	§	Civil Action No. 3:20-CV-02872-X
	§	
MEDTRONIC, INC., et al.	§	
	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER

The plaintiff, Debra Sims, sued Medtronic[1] after she developed a granuloma formation around the tip of her Medtronic SynchroMed II Infusion System (SynchroMed II). The SynchroMed II is a medical device that delivers medication to the intrathecal space around the spinal cord to manage pain. Medtronic moved to dismiss Sims's amended complaint, arguing that her claims are expressly preempted. [Doc. No. 14]. After careful consideration, and as discussed below, the Court **GRANTS** Medtronic's motion to dismiss and **DISMISSES** Sims's amended complaint **WITHOUT PREJUDICE**.

I. Background

Congress passed the Medical Device Amendments of 1976 (the MDA) following the Dalkon Shield failure and its aftermath.[2] The MDA limited state obligations and

[1] References to "Medtronic" include the following defendants: Medtronic, Inc., Medtronic USA, Inc., Medtronic Puerto Rico Operations Co., and Medtronic Logistics, LLC.

[2] *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315–16 (2008) (citing 21 U.S.C. § 360c *et seq.*).

"imposed a regime of detailed federal oversight."[3] This new scheme established oversight for medical devices based on their risk levels. Class III devices, like the SynchroMed II, are "'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,' or 'presents a potential unreasonable risk of illness or injury.'"[4] Class III devices undergo premarket approval, which typically involves a multivolume application including information on safety, effectiveness, and manufacturing, as well as proposed labeling.[5] The Food and Drug Administration spends, on average, 1,200 hours reviewing each application, weighs the risks and benefits, and grants premarket approval only if it finds a "reasonable assurance" of "safety and effectiveness."[6]

Sims has a history of "cervical and lumbar radiculopathy, low back pain, and neck pain."[7] As a result, her first SynchroMed II was implanted in 2008 to assist with pain management. In 2015, she received a new SynchroMed II because the 2008 device suffered from low battery and expired lifecycle. That year, Sims began experiencing symptoms including "insomnia, nighttime pain, restless legs, sweats, as well as depression, nausea, and weakness."[8] Sims's MRI scan revealed the

[3] *Id.* at 316.

[4] *Id.* at 317 (quoting § 360c(a)(1)(C)(iii)).

[5] *See id.* at 317–18.

[6] *See id.* at 318 (quoting § 360e(d)).

[7] Doc No. 13 at 4.

[8] Doc. No. 13 at 5.

development of a granuloma[9] around the tip of the SynchroMed II. Her doctor suggested inserting a new catheter and restarting her pain-medication infusion because removing the SynchroMed II posed a risk to her health and mobility. Sims claims that due to "defects and malfunction," the "SynchroMed II Device and catheter failed, forming a granuloma mass in the area of her spine where the catheter meets with the spine."[10] She brought four claims against Medtronic: (1) strict liability manufacturing defect; (2) negligent manufacturing defect; (3) breach of implied warranty; and (4) punitive damages.

II. Legal Standards

Under Federal Rule of Civil Procedure 12(b)(6), the Court evaluates the pleadings by "accepting all well-pleaded facts as true and viewing those facts in the light most favorable to the plaintiff."[11] To survive a motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'"[12] A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged."[13] Although the plausibility standard

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[9] In the context of intrathecal drug-delivery systems, like the SynchroMed II, a granuloma "can block the catheter-tip [and] hinder drug delivery causing ineffective pain management. More seriously, the lesion can lead to compression of the spinal cord causing permanent neurological deficit." *See* Moritz Hearing, Christian Saleh, Phillip Jaszczuk, Markus Koehler, Margret Hund–Georgiadis, *Intrathecal Pump Catheter-tip Granuloma Recurrence with Associate Myelomalacia—How Safe is Intrathecal Analgesic Infusion Therapy?*, SURGICAL NEUROLOGY INTERNATIONAL (2019).

[10] Doc. No. 13 at 7.

[11] *Stokes v. Gann*, 498 F.3d 483, 484 (5th Cir. 2020).

[12] *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

[13] *Iqbal*, 556 U.S. at 678.

does not require probability, "it asks for more than a sheer possibility that a defendant has acted unlawfully."[14] In other words, the standard requires more than "an unadorned, the-defendant-unlawfully-harmed-me accusation."[15] "A pleading that offers 'labels and conclusions' or a 'formulaic recitation of the elements of a cause of action will not do.'"[16]

The MDA expressly preempts only state requirements that are "different from, or in addition to, any requirement applicable . . . to the device under federal law, §306k(a)(1)."[17] So, to determine whether a state requirement is expressly preempted, courts must conduct a two-step analysis: (1) determine whether the federal government established requirements applicable to the device at issue; and (2) if so, determine whether the state law claims at issue are based upon requirements that are "'different from, or in addition to,' [federal requirements], and that relate to safety and effectiveness."[18] But section 306k "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements."[19]

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[14] *Id.*; *see also Twombly*, 550 U.S. at 555 ("Factual allegations must be enough to raise a right to relief above the speculative level[.]").

[15] *Iqbal*, 556 U.S. at 678.

[16] *Id.* (quoting *Twombly*, 550 U.S. at 555).

[17] *Riegel*, 552 U.S. at 321.

[18] *Id.* at 321–22.

[19] *Id.* at 330.

III. Analysis

Medtronic argues that the Court should dismiss Sims's case with prejudice because her claims are preempted. Sims disagrees, contending that her claims are parallel and therefore not preempted. To determine whether the claims are preempted, the Court must conduct the two-part test explained in *Riegel*.

First, the Court finds that the federal government did establish requirements applicable to the SynchroMed II. This is so because the SynchroMed II is a Class III device granted premarket approval. As the Supreme Court explained in *Riegel*, "premarket approval is specific to individual devices."[20] Because the FDA thoroughly reviews all devices undergoing the premarket-approval process, premarket approval "imposes 'requirements' under the MDA[.]"[21] Having found that the federal government established requirements applicable to the SynchroMed II, the Court proceeds to the second inquiry: whether Sims's claims rest upon state law that is different from, or in addition to, federal requirements and that relates to the safety or effectiveness of the device.

This Court has previously found "*Riegel* stands for the proposition that statutory or common law causes of action that would impose different or additional duties relating to any requirement imposed by the [premarket approval] of a device are expressly preempted."[22] In order to survive the motion to dismiss stage, Sims

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[20] *Id.* at 323.

[21] *Id.* at 322.

[22] *Steen v. Medtronic*, No. 3:10-CV-936-L, 2010 WL 2573455, at *4 (N.D. Tex. June 25, 2010) (Lindsay, J.).

must plead state law claims plausibly showing that Medtronic deviated from the premarket approval requirements specific to the SynchroMed II.[23] To properly do so, Sims cannot "simply incant the magic words" that Medtronic "violated FDA regulations."[24] Instead, she must "specify a causal connection between the failure of the specific manufacturing process and the specific defect in the process that caused the personal injury."[25]

Sims's amended complaint identifies thousands of adverse events Medtronic reported from 2012 until 2019, many of which related to catheters. It also explains that Medtronic, "in [its] manufacture of the SynchroMed II Device (including not only the pump but also catheters), violated federal law governing manufacture and quality control of PMA medical devices . . . ."[26] Following those inspections, the FDA issues warning letters to Medtronic, identifying violations, which culminated in an injunction which stopped the "manufacture, sale, and distribution of the SynchroMed II . . . ."[27] The SynchroMed II and its components have also been recalled at least 77 times.[28]

The Court notes that Sims's complaint—which shows deviations identified by the FDA including adulteration, failure to establish adequate procedures for

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[23] *See Yosowitz v. Covidien LP*, 182 F. Supp. 3d 683, 691 (S.D. Tex. 2016) (cleaned up).

[24] *Id.* at 692 (cleaned up).

[25] *Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011).

[26] Doc. No. 13 at 18.

[27] *Id.*

[28] The Court recognizes that recalls are not necessarily indicative of deviations from premarket approval requirements.

corrective and preventive action, and misbranding—plausibly alleges facts sufficient to demonstrate that Medtronic deviated from premarket approval requirements. And it also plausibly shows that at least some of those deviations were with respect to the SynchroMed II.

Sims explains that "at least one of the catheter recalls further explains and demonstrates the manufacturing defects that caused" her allegedly malfunctioning device. The FDA issued that particular recall in 2008 after Medtronic received reports "of inflammatory mass formations at or near the distal tip of intrathecal catheters which infuse opioids . . . ."[29] Sims claims that the recall is representative of the "existing and recurring issues" the SynchroMed II was experiencing and Medtronic's knowledge of those issues.[30]

Identifying a specific recall, however, is not tantamount to identifying a specific manufacturing process and the specific defect within that process that caused her personal injury. While Sims's complaint plausibly alleges deviations in various manufacturing processes, it fails to allege facts which plausibly show a specific defect in a specific process that caused her injury. Merely noting the existence of a recall does not suffice to state a defect in a specific process. The possibility of adverse side effects which result in a recall does not necessarily mean that there was any defect that caused an injury.

[29] Doc. No. 13 at 34.

[30] *Id.* at 35.

In order to adequately plead a parallel claim, Sims was required to plausibly show "the existence of a manufacturing defect caused by a violation of federal regulations *and* allegations connecting a defect in the manufacture of the specific device to [Sims's] specific injury."[31] While Sims identified manufacturing defects, she did not connect a *specific* defect to her *specific* injury. Instead, she identified a relevant recall. But a recall does not outline specific defects, nor does it necessarily imply that a defect even existed.[32]

IV. Conclusion

For the foregoing reasons, the Court **GRANTS** Medtronic's motion to dismiss and **DISMISSES** Sims's claims **WITHOUT PREJUDICE**. If Sims wishes to file an amended complaint, she must do so within thirty days of the entry of this order.

IT IS SO ORDERED this 4th day of June 2021.

BRANTLEY STARR
UNITED STATES DISTRICT JUDGE

[31] *Bass v. Stryker Corp.*, 669 F.3d 501, 511–12 (5th Cir. 2012).

[32] Sims admits in her response that "FDA warning letters and recalls are not themselves violations of Federal law." Doc. No. 17 at 13.